- Disclaimer -

The ViSi Mobile Patient Monitoring System is in late stage development and has <u>NOT</u> been cleared by the FDA. All of the features and capabilities described in this presentation are design goals. There is no guarantee that the system as described will be cleared by the FDA for market release.

Sotera Overview

- Founded 2004 – 38 current employees

- Funded by Qualcomm, Intel, West Family Holdings, Sanderling and Apposite

- Initial Goal: continuous non-invasive blood pressure

- Current focus: a body-worn wireless monitoring platform

- 1st ViSi Mobile 510(k) expected to be filed in 2010

Not yet FDA cleared

Sotera WIRELESS

The Challenging Future

- Population over 65 is projected to grow from 37M to 71.5M by 2030[1,2]

- Older Americans now account 35% of hospital stays[3]

- 77% of older Americans have multiple chronic conditions[4]

- Number of hospital beds per capita has been on decline[5]

[1] agingstats.gov.
[2] U.S. Census Bureau
[3] AHRQ, HCUPnet 2008
[4] May, 2008 report from the U.S. Department of Health and Human Services (HHS)
[5] American Hospital Association

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Current healthcare model must evolve

- Site-specific model will change to provide higher acuity services in non-hospital settings

- Mobile + wireless technologies are essential in making this possible (including 3G networks)

- EHRs alone are not enough – medical technology must foster mobility and flexibility

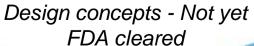- Continuous monitoring in real time, anywhere, for the patient and the clinician is key

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Future: ViSi Mobile Patient Monitoring System

Design Goals

- Continuous vital signs +
  - Non-invasive continuous blood pressure (cNIBP)
  - Respiration
  - SpO_2
  - HR/PR
  - ECG
  - Temp (skin)
- Motion/ activity
- Location

Design concepts - Not yet FDA cleared

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Hospital: detecting patient deterioration without restricting mobility
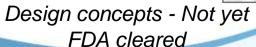
ViSi Monitor

ViSi Server

Ethernet

- 802.11 with EMR connectivity
- Utilizes existing infrastructure
- 802.11 to 3G enables fully mobile access outside hospital (e.g. Airstrip, mVisum)

Design concepts - Not yet FDA cleared

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Proliferation of wireless devices requires new standards/ testing guidelines

Nurse Call

Vital Signs Monitoring

Patient/ Device Location

Computer on wheels

Voice Communication (VoIP)

Bar coded medication administration

WLAN today…

- QoS, security tools exist
- Reliability approaching wired LANs
- Present in >90% of hospitals

Weak links…

- Ad hoc interoperability testing
- Ad hoc network load and coexistence testing
- Network planning/ management
- WLAN ⟷ WWAN connectivity

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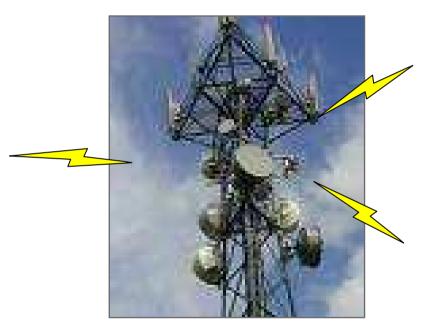WIRELESS

Recommendations - Hospitals

- Avoid licensing new dedicated bandwidth in hospitals (e.g. WMTS)
  - Need ability to use low cost wireless components that are used in mainstream commercial applications
  - Fosters proprietary networks

- IEC 80001 is an important step particularly for life-critical networks

- Borrow heavily from non-medical wireless standards/conventions
  - Interoperability (e.g. WiFi Alliance certification)
  - Coexistence (e.g.Veriwave)

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Outpatient: monitoring will be continuous and in real time

Doctor or family member

Service center

Design concepts - Not yet FDA cleared

Recommendations - Outpatient

- Encourage carriers to provide QoS and service-level agreements for life-critical channels (medical alerts etc.)

- Avoid dedicated, health-only spectrum – mHealth devices could become unaffordable.

- Leverage the 3G ecosystem.

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Challenges

- QoS/ reliability when roaming
  - From private to public networks
  - Vertically (e.g. from 802.11 to 3G)
  - Coverage

- Life-critical networks
  - Verification and validation

- Proliferation of wireless technologies
  - Keeping domain knowledge up to date

- Uniform testing guidelines for wireless medical devices
  - Interoperability
  - Coexistence
  - Load

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